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REMARKS/ARGUMENTS

Applicants respectfully note again that the Attorney Docket Number for this application has been changed from 20164000US5 to ARG010RC. Applicants respectfully request correction of the Attorney Docket Number for this application.

Applicants acknowledge with appreciation the withdrawal of the previous rejections of claims under 35 U.S.C. §112, first paragraph (Office Action, page 2).

Although Applicants do not believe that any of these cases are relevant to the present claims, Applicants note copending App. No. 10/287,813 and copending App. No. 08/600,483. The Examiner is believed to be aware of App. No. 10/287,813, as it claims priority to the same application as the instant case and was also the subject of a provisional obviousness-type double patenting rejection earlier in prosecution of the instant case; this rejection was later obviated by cancellation of claims in the copending case and was withdrawn (see Final Rejection dated 13 December 2006, page 2, #3)). Applicants do not believe that copending App. No. 08/600,483 is relevant to the present claims, but the Examiner in App. No. 10/287,813 made a provisional obviousness-type double patenting rejection of claims in that case over certain claims of U.S. Pat. No. 7,198,948, which issued from App. No. 10/047,072, which claims priority of pending App. No. 08/600,483. In response to that rejection, in order to advance prosecution, Applicants filed a terminal disclaimer.

Claims 89, 91, 92, 94, 95, 99, 101, 103-113, 115-121 and 140-144 are pending in the application. Independent claims 101 and 120 have been amended to clarify that the claims are directed to compositions comprising mature dendritic cells. The remaining claims depend from or incorporate the limitations of claim 101 and so have also been amended in the same manner.

Support for these amendments can be found throughout the priority application (No. 07/861,612), for example, on page 2, lines 7-9, which state that "a method is provided for culturing proliferating dendritic cell precursors and for their maturation *in vitro* to mature dendritic cells." The same statement is found in the present specification on page 1, lines 19-21, and support has been acknowledged in the Office Action (Office Action of 2 August 2007, page 4, third full paragraph). Support can also be found in the priority application in original independent claim 17 and original dependent claim 36, which were as follows:

17. A method of producing a population of mature dendritic cells from proliferating cell cultures comprising:

a) providing a tissue source comprising dendritic cell precursors;

b) treating the tissue source to obtain a population of cells suitable for culture *in vitro*;

c) culturing the tissue source on a substrate in a culture medium comprising GM-CSF to obtain nonadherent cells and cell clusters;

d) subculturing the nonadherent cells and cell clusters to produce cell aggregates comprising proliferating dendritic cell precursors;

e) serially subculturing the cell aggregates one or more time to enrich the proportion of dendritic cell precursors; and

f) continuing to culture the dendritic cell precursors for a period of time sufficient to allow them to mature into mature dendritic cells.

36. A composition comprising antigen-activated dendritic cells wherein dendritic cells prepared according to claim 17 are pulsed with an antigen and wherein the dendritic cells process the antigen to produce a modified antigen which is expressed by the dendritic cells.

In view of the above discussion, Applicants respectfully submit that the present amendments to the claims meet the requirements of 35 U.S.C. § 112 and that no new matter has been added. Reexamination and reconsideration of the claims are respectfully requested.

The Invention

"The present invention provides for the first time a method of obtaining dendritic cells in sufficient quantities to be used to treat or immunize animals or humans with dendritic cells which have been activated with antigens" (specification at page 40, lines 25-28 and page 9, line 35 through page 10, line 4). Specifically, the invention provides "a method of producing cultures of proliferating dendritic cell precursors which mature *in vitro* to mature dendritic cells. The dendritic cells and the dendritic cell precursors produced according to the method of the invention may be produced in amounts suitable for various immunological interventions for the prevention and treatment of disease" (see the specification at page 19, lines 25-31 (the first paragraph of the Detailed Description of the Invention)). In this manner, the invention overcomes the previously existing problem in the art of not being able to obtain sufficient quantities of dendritic cells in culture for clinical treatment (as discussed, for example, in the

Background section on page 2, second paragraph, and on page 8, lines 8-10). Further, dendritic cells produced by a method of the invention are "much more potent in presenting antigens to primed T cells than corresponding cultures of mature dendritic cells...." (see, *e.g.*, page 37, lines 17-20).

The Rejection of Claims under 35 U.S.C. § 102(a) Should Be Withdrawn

The Office Action (page 2, #5) has maintained the rejection of claims 89, 91, 92, 94, 95, 99, 101, 103-113, 115-121, and 140-144 under 35 U.S.C. § 102(a) over Pancholi *et al.* (1992) *Immunology* 76: 217-224. Applicants respectfully traverse this rejection.

The Office Action states (page 3, second full paragraph) that the rejection over the Pancholi reference is maintained because although the Pancholi reference was published after the priority date of the present application, the "claimed cells are not supported by the instant specification [and] they are not supported by the priority documents, thus the priority date of the instant application is its filing date, 05/06/1998."

Applicants note that claims 101 and 120 have been amended to clarify that they are directed to compositions comprising mature dendritic cells. The remaining claims depend from or incorporate the limitations of claim 101 and so have also been amended in the same manner.

In view of these claim amendments and the discussion above regarding support for the amendments in the present specification and in the priority application, Applicants respectfully submit that the claims as amended are fully supported by the specification and the priority application. Accordingly, the priority date that should be accorded to the present claims is the official priority date of 1 April 1992. Because the Pancholi reference was published after this date, it should not be citable against the present claims under 35 U.S.C. § 102(a), and Applicants respectfully submit that this rejection of claims should be withdrawn.

Nevertheless, Applicants further note that, as discussed previously in detail in this case (*e.g.*, in the Amendment filed 11 April 2007), the process used to make Applicants' claimed cells is different from the process described by Pancholi, and the cells that result from Applicants' different process are also different from the cells described by Pancholi. Thus, Pancholi does not teach the cells of the present invention. This argument was presented in detail in the previously-

filed Amendment and is not reiterated here because Applicants believe that the remaining objections to the claims are fully addressed by the present claim amendments.

In view of the above discussion, Applicants respectfully request that the rejection of claims over the Pancholi reference for lack of novelty be withdrawn.

The Claims Meet the Requirements of 35 U.S.C. §112, First Paragraph

The Office Action has rejected claims 89, 91, 92, 94, 95, 99, 101, 103-113, 115-121, and 140-144 under 35 U.S.C. § 112, first paragraph (Office Action of 2 August 2007, page 3, #8). Applicants respectfully traverse this rejection.

The Office Action states that the rejected claims fail to meet the written description requirement because the specification and claims as originally filed do not provide support for the invention as now claimed. Applicants respectfully disagree with this conclusion.

Applicants note that claims 101 and 120 have been amended as discussed above to clarify that they are directed to compositions comprising mature dendritic cells. The remaining claims depend from or incorporate the limitations of claim 101 and so have also been amended in the same manner.

In view of these claim amendments and the support for these amendments in the present specification and the priority application as discussed above, Applicants respectfully submit that the claims as amended are fully supported as required by 35 U.S.C. § 112. Accordingly, this rejection of the claims has been obviated by amendment and should be withdrawn.

CONCLUSION

In view of the foregoing remarks, Applicants respectfully submit that all rejections have been overcome and that the claims are in condition for allowance. However, if the Examiner believes that any further discussion of this communication would be helpful, he is encouraged to contact the undersigned by telephone.

A one-month extension of time is believed to be due in connection with this communication. However, if any additional extensions of time are necessary for the consideration of this paper, such extensions are petitioned under 37 CFR § 1.136(a). Please

apply any charges that may be due for extensions of time or for net addition of claims to our Deposit Account No. 50-3187.

Respectfully submitted,

Leigh W. Thorne, Ph.D.
Attorney for Applicants
Registration No. 47,992

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8 (a)

I hereby certify that this correspondence is being transmitted via facsimile (571-273-8300) to the United States Patent and Trademark Office on the date set forth below.

NOV. 29, 2007
Date

Alida M. Clark